Press Release

Climedo and TRIGA-S Launch Survey on the Status of IVDR Implementation

Munich, 03 March, 2022. Software company Climedo and contract research institute TRIGA-S Scientific Solutions have published a survey on the European In Vitro Diagnostics Regulation (EU-IVDR 2017/746). The survey is aimed at diagnostics manufacturers of all sizes and product classes. The purpose of the survey is to determine the status of implementation of the IVDR requirements and any potential need for further information.

Where do diagnostics manufacturers stand three months before the IVDR comes into force? What are the biggest challenges and what do companies need to better prepare for implementation? These and other questions are addressed in the joint survey, which will run until March 31. With the IVDR coming into force on May 26, 2022, diagnostics manufacturers face numerous new challenges in getting their products to market and keeping them there. The EU Commission's recent extension of transitional periods for certain product classes has offered some relief to manufacturers. From the date of application, however, stricter vigilance and market surveillance requirements must be met for all products, including those which are subject to the transitional periods.

"Climedo regularly works manufacturers who wish to implement the IVDR requirements promptly, and we have already seen very good progress," says Veronika Schweighart, Co-Founder, and COO of Climedo. “Nevertheless, we have a lot of work ahead of us. With the new regulation, it will be essential for companies to switch to digital solutions for their data capture processes. We look forward to evaluating the results and publishing them shortly.”

Dr. Andreas Franke, COO at TRIGA-S, says: "For us as a service provider specializing in IVD performance studies, our clients' understanding of the new regulatory requirements is crucial. The joint survey with Climedo will provide us with important first-hand feedback on the status of the implementation of the IVDR from the IVD industry.”

The survey consists of 16 questions and takes 5-10 minutes at most. Among others, the survey addresses the following areas:

- Understanding of IVDR requirements
- Status of implementation
- Challenges
- Notified Bodies
- EUDAMED
- Impact of COVID-19

- Need for support

The results of the survey will be evaluated anonymously and then published. On request, survey respondents will receive the evaluation by email.

The survey is now available here.

About Climedo
Climedo offers a digital platform for conducting clinical trials in an innovative way. The modular solution for Electronic Data Capture (EDC) enables pharmaceutical and medical device companies to efficiently validate their products and medical innovations in a decentralized and patient-centric way. By digitally connecting all parties involved, such as sponsors, doctors and patients, communication and data capture can be significantly simplified. The digital health company was founded in 2017 by Sascha Ritz, Dragan Mileski and Veronika Schweighart and is based in Munich. Learn more at www.climedo.com.

About TRIGA-S
TRIGA-S Scientific Solutions (TRIGA-S) stands for quality and trustful collaboration in clinical and analytical studies for in vitro diagnostics (IVD) since over 20 years. As part of the new EU regulation IVDR, TRIGA-S offers manufacturers tailor-made solutions for performance studies. In addition, they plan and conduct exploratory and feasibility studies. In their in-house BSL2 laboratory, they carry out contract measurements and offer controlled storage and shipping options for human samples and study materials. TRIGA-S is based in Habach, south of Munich, is ISO 13485 certified and was awarded "Bavaria's Best 50" in the SME category in 2020. For further information, visit: www.triga-s.de.

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